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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,852	06/01/2001	Paul B. McCray JR.	IOWA:031US	1110
7590	04/20/2004			EXAMINER
Steven L. Highlander Fulbright & Jaworski L.L.P. Suite 2400 600 Congress Avenue Austin, TX 78701			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 04/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Hope A. Robinson

1053

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 09 February 2004.  
2a) This action is **FINAL**.                    2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,3,4,11,12,14-24,28,29 and 31 is/are pending in the application.  
4a) Of the above claim(s) 1-12 and 14-24 is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 1,3,4,28,29 and 31 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Interview Summary (PTO-1441)

## **DETAILED ACTION**

1. Applicant's response to the Office Action mailed November 4, 2003 on February 9, 2004 is acknowledged.
2. Claims 2, 5-10, 13, 25-27, 30 and 32-55 have been canceled. Claims 1, 3, 4, 11, 19, 28 and 31 have been amended. Claims 1, 3-4, 11-12, 14-24, 28-29 and 31 are pending. Claims 1, 3-4, 28-29 and 31 are under examination.
3. The following grounds of rejection are or remain applicable:

### ***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 3-4 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 3 lacks antecedent basis for "said pharmaceutically acceptable composition" as the claim now depends from claim 1 which only recites pharmaceutical

Claim 4 is indefinite because the claim as amended depends from amended claim 1, and claim 4 does not further limit independent claim 1. Claim 1 recites pharmaceutical composition (for example, as a pharmaceutical composition, it includes the unrecited carrier) and to then explicitly recite same in claim 4 does not appear to more narrowly define the invention (see also claim 3).

Amended claim 31 is indefinite because the claim does not further limit claim 28 which recites that the peptide is contained in a pharmaceutical composition, (for example, as a pharmaceutical composition, it includes the unrecited carrier) and to then explicitly recite same in claim 31 does not appear to more narrowly define the invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3-4, 28-29 and 31 remain rejected under 35 U.S.C 102(b) as being anticipated by Adler et al. (WO 99/13080, March 18, 1999).

Adler et al. disclose the claimed peptide (claims 1, 28 and 29). The sequence reported by the reference is 100% identical to the sequence set forth in SEQ ID NOs:2, 3 and 4 and as claims 1, 28 and 29 recite the open language "comprising" (see SEQ ID NO: 1 of the reference) the reference sequence anticipates the claims and that the composition can be administered topically (claim 4). Adler et al. also teach a

pharmaceutical composition and acceptable carrier (claims 3 and 31) see page 56 of the reference. Thus, the claimed invention is anticipated by this reference.

6. Applicant's arguments filed February 9, 2004 has been considered. Applicant's comments regarding a rejoinder of method claims pending notification of an allowable product are noted. However, the amendments to the claims were not sufficient to obviate the rejections of record. The response on page 9 states that claims 1, 11, 19 and 28 have been amended to include the limitation of objected claims 5 and 33, namely oral formulation. Thus, it is believed that the amended claims are novel over the cited reference by Adler et al. Applicant's comments are noted, however, are not accurate. The claims have been amended to recite "topical administration" not "oral administration" which is taught by Adler et al., thus are not novel. Therefore, the rejection remains.

Note the new ground of rejection instituted under 35 U.S.C. 112, second paragraph based on applicant's amendments to the claims. Claim 4 does not further limit claim 1 as the limitation of claim 4 is now encompassed in amended claim 1.

An interview summary is attached to clarify the record that applicant intends to cancel the above noted claims as the text appeared in the claim listing. Applicant is reminded that the revised amendment practice indicates that "no text is to appear for canceled or not entered claims".

### ***Conclusion***

7. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on 571-272-0951. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner

  
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